Complete Summary

GUIDELINE TITLE

Undifferentiated vaginal bleeding/abdominal pain suggestive of ectopic pregnancy clinical pathway.

BIBLIOGRAPHIC SOURCE(S)

Emergency Medicine Quality Council. Undifferentiated vaginal bleeding/abdominal pain suggestive of ectopic pregnancy clinical pathway. Portland (ME): Maine Medical Center, Department of Emergency Medicine; 2006 Aug. 5 p.

GUIDELINE STATUS

This is the current release of the guideline.

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Ectopic pregnancy

GUIDELINE CATEGORY

Diagnosis Evaluation Screening

CLINICAL SPECIALTY

Emergency Medicine Obstetrics and Gynecology Radiology

INTENDED USERS

Advanced Practice Nurses Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To present a clinical pathway for the evaluation of women of childbearing age who present to the emergency department with abdominal pain and/or vaginal bleeding suggestive of ectopic pregnancy

TARGET POPULATION

Women of childbearing age with abdominal pain and/or vaginal bleeding suggestive of ectopic pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Screening with urine pregnancy test
- 2. Quantitative beta chorionic human gonadotropin serum testing
- 3. Transvaginal ultrasound
- 4. Blood typing and screening
- 5. Serum hematocrit testing
- 6. Referral to specialists as necessary

MAJOR OUTCOMES CONSIDERED

- Risk factors associated with ectopic pregnancy
- Sensitivity and specificity of diagnostic tests
- Incidence of heterotopic pregnancy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE and CINAHL databases and the Cochrane Library were used to conduct a literature search to locate relevant articles. The search was restricted to articles published in the English language. Priority was given to articles reporting

results of original research although review articles and commentaries were also reviewed. Hand searches of relevant journals were conducted to locate relevant articles. Hand searches of the references of relevant articles were conducted to locate related articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

- **A1** = Evidence from well-designed meta-analysis or well-done systematic review with results that consistently support a specific action
- **A2** = Evidence from one or more randomized controlled trials with consistent results
- **B1** = Evidence from high quality evidence-based practice guideline
- **B2** = Evidence from one or more quasi experimental studies with consistent results
- **C1** = Evidence from observational studies with consistent results (e.g., correlational, descriptive studied)
- **C2** = Inconsistent evidence from observational studied or controlled trials
- **D** = Evidence from expert opinion, multiple case reports, or national consensus reports

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This guideline was developed from a systematic review and synthesis of current evidence on ectopic pregnancy. Research findings and other evidence, such as guidelines, clinical policies, and standards from professional organizations, case reports, and expert opinion, were critiqued, analyzed, and used as supporting evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was reviewed by experts knowledgeable of research on ectopic pregnancy and guideline development.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The major recommendations for the emergency department management of women of childbearing age presenting with undifferentiated vaginal bleeding and/or abdominal pain suggestive of ectopic pregnancy are provided in the form of an algorithm, "Undifferentiated Vaginal Bleeding/Abdominal Pain Suggestive of Ectopic Pregnancy Clinical Pathway."

The grades of the strength and consistency of evidence (A1, A2, B1, B2, C1, C2, D) are defined at the end of the "Major Recommendations" field.

Definitions

Quantitative beta human chorionic gonadotropin (beta-hCG): expressed in mIU/mL per the World Health Organization Third International Standard (International Reference Preparation)

Clinical Evaluation

Data suggest that women with normal intrauterine pregnancies rarely experience pain or vaginal bleeding at below-threshold beta-hCG levels (1,000, 1,500, or 2,000 mIU/mL) and that women who do present to the emergency department (ED) with pain and/or vaginal bleeding and low beta-hCG levels are much more likely to have ectopic or abnormal intrauterine pregnancies (Kohn et al., 2003).

Therefore, a conservative approach to the evaluation of women of childbearing age presenting to the ED with abdominal pain and/or vaginal bleeding suggestive of ectopic pregnancy has been adopted.

- Women of childbearing age presenting to the ED with abdominal pain and/or vaginal bleeding will receive a urine test for pregnancy at triage ("Clinical policy," 2000. Evidence Grade = B1).
- Women with positive urine pregnancy tests who have not previously had an intrauterine pregnancy document by ultrasound will receive quantitative beta-hCG testing and a formal endovaginal ultrasound (Bloch, Baumann, & Strout, 2006; Dart, Kaplan, & Cox, 1997; Kaplan, et al., 1996. Evidence Grade = C1).
- Women with vaginal bleeding will also undergo blood type and screen for Rh as well as hematocrit evaluation (Royal College of Obstetricians & Gynaecologists, 2004; "Clinical policy," 2003. Evidence Grade = B1).
- Endovaginal ultrasound will not be dependent upon beta-hCG level (Gracia & Barnhart, 2001. Evidence Grade = B2)
- For women without intrauterine pregnancy observed by endovaginal ultrasound, an Obstetrics/Gynecology consult will be obtained (Tayal, Cohen, & Norton, 2004. **Evidence Grade = D**).

General Considerations

- Always consider the possibility of heterotopic gestation, particularly in women who have utilized assisted reproductive technologies such as in vitro fertilization or gamete intrafallopian transfer (Dimitry et al., "Heterotopic pregnancy," 1990; Dimitry et al., "Nine cases of heterotopic pregnancies," 1990; Molloy et al., 1990. Evidence Grade = D).
- For women who have conceived naturally, the presence of an intrauterine pregnancy makes the likelihood of ectopic pregnancy extremely rare as the incidence of heterotopic gestation has been reported to be between 1 in 4,000 and 1 in 8,000 (Hann, Bachman, & McArdle, 1984; Reece et al., 1983; Bello et al., 1986; van Dam, Vanderheyden, & Uyttenbroeck, 1988; Vanderheyden & van Dam, 1987. **Evidence Grade = D**).
- It should be noted that several studies have shown a prevalence of normal ultrasound examination in 5% to 27% of women who actually have ectopic pregnancy (Stabile, Campbell, & Grudzinskas, 1988; Mahoney, et al., 1985; Nyberg et al., 1987. **Evidence Grade = C1**).

Definitions:

Evidence Grading

A1 = Evidence from well-designed meta-analysis or well-done systematic review with results that consistently support a specific action

A2 = Evidence from one or more randomized controlled trials with consistent results

B1 = Evidence from high quality evidence-based practice guideline

- **B2** = Evidence from one or more quasi experimental studies with consistent results
- **C1** = Evidence from observational studies with consistent results (e.g., correlational, descriptive studied)
- **C2** = Inconsistent evidence from observational studied or controlled trials
- **D** = Evidence from expert opinion, multiple case reports, or national consensus reports.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for undifferentiated vaginal bleeding/abdominal pain suggestive of ectopic pregnancy clinical pathway.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of undetected ectopic pregnancy
- Prevention of ruptured ectopic pregnancy
- Decreased morbidity and mortality associated with ectopic pregnancy

POTENTIAL HARMS

- Discomfort associated with phlebotomy
- Infection risk associated with phlebotomy
- Invasive nature of endovaginal ultrasound

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

• This evidence-based clinical pathway is only a guide. It is highly recommended that all hospital emergency departments develop a plan for the evaluation of women at risk for ectopic pregnancy based upon available

- resources. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or practice setting.
- This (algorithm) tool is intended to be a reference for clinicians caring for patients with undifferentiated vaginal bleeding or abdominal pain suspicious for ectopic pregnancy and is not intended to replace providers' clinical judgment. Some clinical problems may not be adequately addressed by this reference. Always assess for other causes of abdominal pain.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The guideline developer's implementation strategy includes:

- Educational sessions on clinical pathway implementation
- Distribution of the clinical pathway to all emergency physicians and nurses
- Distribution of the clinical pathway to all radiology physicians and staff

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Emergency Medicine Quality Council. Undifferentiated vaginal bleeding/abdominal pain suggestive of ectopic pregnancy clinical pathway. Portland (ME): Maine Medical Center, Department of Emergency Medicine; 2006 Aug. 5 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

Maine Medical Center, Department of Emergency Medicine - Hospital/Medical Center

SOURCE(S) OF FUNDING

Maine Medical Center, Department of Emergency Medicine

GUIDELINE COMMITTEE

Emergency Medicine Quality Council: Ectopic Pregnancy Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Rebecca B. Bloch, MD, Attending Physician Emergency Medicine; Michael R. Baumann, MD, Vice Chair and Medical Director Emergency Medicine; Tania D. Strout, RN, BSN, Research Nurse Emergency Medicine

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Maine Medical Center</u>, <u>Department of Emergency Medicine Web site</u>.

Print copies: Available from Maine Medical Center Department of Emergency Medicine Research Office, 321 Brackett Street, Portland, ME 04102. Telephone: (207) 662-7049. Contact: Tania D. Strout, RN, BSN at Strout@mmc.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 8, 2006. The information was verified by the guideline developer on December 12, 2006.

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Date Modified: 9/15/2008

